MAY 23 2008

K080842 #1/2

Apex Knee System **April 16, 2008**

1. **Submitter:** OMNI life science™, Inc.
175 Paramount Drive
Raynham, MA 02767

Contact: Mr. William S. McCallum
Director of Regulatory and Quality Systems
(508) 824-2444 (voice)
(508) 822-6030 (fax)

2. Device Name

Proprietary Name:	Apex Knee System Porous Coated Tibial Components
Common Name:	Total Knee Replacement Prosthesis
Classification Names:	Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer Prosthesis, knee, patellofemorotibial, semi-constrained, uncemented, polymer/metal/polymer
Regulatory Classes:	Class II per 21 CFR §888.3560 Class II (special controls) per 21 CFR §888.3565
Product Codes:	JWH, MBH

3. Intended Use

The Apex Knee System is intended for use as a primary or revision total knee replacement. This prosthesis may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed.

The porous coated femoral component may be used cemented or uncemented (biological fixation). The porous coated tibial baseplate component may be used uncemented (biological fixation). All other femoral, tibial baseplate, and patellar components are indicated for cemented use only.

4. Device Description

The Apex Knee System Porous Coated Tibial Components are part of the Apex Knee System for primary or revision total knee replacement. These cobalt chrome tibial components have a plasma sprayed CP titanium porous coating (ASTM F1580) with a plasma sprayed overcoat of hydroxyapatite (ASTM F1185), and are intended for use without bone cement. Fixation of the porous coated tibial component is achieved by biological fixation via tissue ingrowth into the porous coating. The Apex Knee System includes a tibial component option with two holes for supplemental fixation using cancellous bone screws, and the same porous coating. The Apex Knee System consists of a range of sizes of femoral components with a deep patellar groove, dome shaped UHMWPE patella resurfacing components, UHMWPE tibial inserts, cobalt chrome tibial trays, and a titanium alloy bolt for locking the tibial insert to the tibial tray. This modular configuration allows the surgeon user to choose a combination of femoral and tibial tray component sizes to appropriately fit the anatomy of the patient, and to use a tibial insert with a size-for-size match to the femoral component. There are two different articular geometries for

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the tibial insert, a cruciate retaining ("CR") design, which allows retention of the posterior cruciate ligament, and an ultra-congruent posterior cruciate substituting ("Ultra") design. For each tibial insert, a range of UHMWPE thicknesses are available to aid in obtaining the proper soft tissue balance across the knee joint.

5. Predicate Device Comparison

Substantial equivalence is claimed to the Apex Knee System (K060192 and K073602) and the Apex Modular™ HA Hip Stem (K043123), distributed by OMNI life science, Inc. The following table summarizes the similarities and differences between the subject uncemented tibial components of the Apex Knee System and these predicate devices:

	Apex Knee Porous Coated Tibial Components	**Apex Knee System (K060192 and K073602)**	**Apex Modular™ HA Hip Stem (K043123)**
INTENDED USE			
Primary and revision, 3 compartment knee	Yes, cemented or uncemented (porous coated tray: uncemented only)	Yes, cemented (porous coated femoral: cemented or uncemented)	Yes, uncemented (THA)
DESIGN			
Anatomic (asymmetric) tibial tray	Yes	Yes	N/A
Metal-backed UHMWPE tibial component	Yes	Yes	N/A
Tibial insert designs	CR and Ultra	CR and Ultra	N/A
Screw holes	None or two	None	N/A
Tibial tray distal features	Central post and 2 keels	Central post and 2 keels	N/A
MATERIALS			
Tibial component	Cobalt chrome	Cobalt chrome	N/A
Porous coating	Plasma sprayed CP titanium with HA overcoat (tibial tray)	No (tibial tray)	Plasma sprayed CP titanium with HA overcoat (hip stem)

The only change to the Sponsor's predicate Apex Knee System (K060192 and K073602) is the addition of a plasma sprayed CP titanium porous coating with a plasma sprayed overcoat of hydroxyapatite (ASTM F1185) to the tibial components, and the addition of a tibial tray option with the same porous coating and two holes for supplemental fixation using cancellous bone screws. This porous coating is identical to the plasma sprayed CP titanium and hydroxyapatite porous coating on the Sponsor's Apex Modular™ HA Hip Stem (K043123, February 10, 2005). All other materials, designs, and manufacturing, packaging, and sterilization methods are identical to the predicate Apex Knee System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2008

OMNIlife Science
% Bill McCallum
175 Paramount Drive
Raynham, MA 02767

Re: K080842
Trade/Device Name: Apex Knee System, Model KC-230XY, KC-240XY
[no holes, 2 holes]
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer
semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: April 30, 2008
Received: May 02, 2008

Dear Mr. McCallum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: OMNI life science Apex Knee System

Indications For Use:

The Apex Knee System is intended for use as a primary or revision total knee replacement. This prosthesis may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
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Prescription Use__X____ AND/OR Over-The-Counter Use_____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K080842